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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,284	01/02/2002	Masako Izui	217677US0PCT	1454

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,284

Applicant(s)

IZUI ET AL.

Examiner

Elizabeth Slobodyansky, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 3 is/are allowed.
- 6) ☒ Claim(s) 1 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed February 5, 2004 amending claims 1-3 and adding claims 4-7 has been entered.

Claims 1-7 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim has been amended to encompass proteins of any function with an amino acid sequence of 80% or more homologous to SEQ ID NO:2. The specification provides support for proteins with an amino acid sequence of 80% or more homologous to SEQ ID NO:2 and having the sucrose binding activity (page 10, lines 7-11).

However, the examiner is unable to locate adequate support in the specification for a protein having an amino acid sequence of 80% or more homologous to SEQ ID NO:2 that has no disclosed function. Thus there is no indication that proteins with 80% or more homology to SEQ ID NO: 2 and having activities other than activity for binding to

sucrose were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 1 and 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a protein having no defined function and having an amino acid of 80% or more to SEQ ID NO: 2.

Thus, claims 1 encompasses a genus of proteins with an amino acid sequence of 80% or more homologous to SEQ ID NO:2 both naturally occurring and man made. Said genus is a large variable genus encompassing proteins having the sucrose binding activity of the enzyme II of the phosphotransferase system (PTS II) from *Brevibacterium lactofermentum* of SEQ ID NO:2 of the instant invention, activities of other sucrose binding proteins and proteins having neither of these activities that may have other undisclosed functions. Therefore many functionally unrelated proteins are encompassed within the scope of the claim. The specification does not contain any disclosure of the function of all the protein sequences derived from SEQ ID NO:2. The specification discloses only a single species of the claimed genus, the sucrose binding enzyme II of the phosphotransferase system (PTS II) from *Brevibacterium*

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lactofermentum of SEQ ID NO:2 that is encoded by nucleotides 3779-5761 of SEQ ID NO:1, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. One skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Claim 4, with dependent claims 5-7, is drawn to a DNA which hybridizes to nucleotides 3779-5761 of SEQ ID NO:1 under conditions comprising a wash step in 1.0 x SSC, 0.1% SDS at 60° C and which encodes a protein having “an activity for binding to sucrose” (emphasis added). While the recitation of the hybridization conditions provide a structural limitation, the encoded proteins while binding to sucrose may have various activities, *supra*.

The specification does not contain any disclosure of the functions of proteins that bind sucrose or DNAs encoding thereof. The genus of DNAs encoding proteins that comprise these molecules is a large variable genus comprising many functionally diverse proteins. The specification discloses only a single species of the claimed genus, nucleotides 3779-5761 of SEQ ID NO:1 encoding the sucrose binding enzyme II of the phosphotransferase system (PTS II) from *Brevibacterium lactofermentum* of SEQ ID NO:2. Moreover, the specification fails to describe any other representative species encoding proteins binding sucrose and fails to provide any structure: specific function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all

species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1 and 4-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein of SEQ ID NO:2 and a DNA of SEQ ID NO:1, does not reasonably provide enablement for a protein having 80% or more homology to SEQ ID NO:2 both having PTS II function and having no disclosed function and a DNA that hybridizes to nucleotides 3779-5761 of SEQ ID NO:1 under conditions comprising a wash step in 1.0 x SSC, 0.1% SDS at 60° C and which encodes a protein with any activity that binds to sucrose. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is noted that for purposes of this rejection the hybridization conditions recited in claim 4 are considered as conditions under which the claimed DNA encodes a protein having 80% or more homology to SEQ ID NO:2.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins of different strictures and functions that bind sucrose and DNAs encoding thereof.

The specification teaches DNA of SEQ ID NO:1 that encodes an enzyme II of the phosphotransferase system (PTS II) from *Brevibacterium lactofermentum* having the amino acid sequence of SEQ ID NO:2 that is encoded by nucleotides 3779-5761 of SEQ ID NO:1. The specification does not teach any PTS II enzymes or other proteins that bind sucrose and comprise mutations in SEQ ID NO:2 and DNAs encoding thereof. Further, it fails to provide information regarding other combinations of substitute amino acids that would result in a mutant with the requisite characteristics. While there is a great number of possible mutants, it is *a priori* unpredictable as to which mutant will exhibit the claimed property. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The amino acid sequence of a protein determines its structural and functional properties, and predictability of what changes in the amino acid sequence can be tolerated and result in similar activity is extremely complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's structure from

mere sequence data are limited. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of peptide mutants where the expectation of obtaining similar activity is unpredictable based on the instant disclosure.

While binding to sucrose is a feature of various functionally different proteins, the specification does not teach a sucrose binding protein other than the sucrose binding protein that is PTS II of SEQ ID NO:2.

The specification does not support the broad scope of the claims which encompass any PTS II enzyme or any protein that binds sucrose and a DNA encoding thereof because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the requisite activity; (B) the general tolerance of PTS II enzyme to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any PTS II enzyme residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Furthermore, claim 1 comprises proteins having no known function. Without knowing the function, one of ordinary skill in the art would not have known how to use the protein.

Therefore, one of ordinary skill would require guidance, such as information regarding the specific amino acid changes that would retain a PTS II enzyme or any

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other protein activity to bind sucrose, in order to make a PTS II or any protein that binds sucrose having amino acid of 80% or more homologous to SEQ ID NO:2 and a DNA that hybridizes to nucleotides 3779-5761 of SEQ ID NO:1 under conditions comprising a wash step in 1.0 x SSC, 0.1% SDS at 60° C and which encodes a protein having an activity for binding to sucrose in a manner reasonably correlated with the scope of the claims. Further, one of ordinary skill would require guidance, such as information regarding the function of proteins with 80% or more homology to SEQ ID NO:2 in order to use a protein having no disclosed function. Without such guidance, the experimentation left to those skilled in the art is undue.

Allowable Subject Matter

Claims 2 and 3 are allowed.

Response to Arguments

Applicant's arguments filed February 5, 2004 have been fully considered but they are not persuasive.

With regard to the 112, 1st paragraph, written description rejection, Applicants argue that "sufficient structural definition in the claims, and combined with the functional limitation regarding sucrose binding activity, applicant's assert that one skilled in the art is able to reasonably conclude that applicants were in possession of the claimed invention at the time the instant application was filed" (Remarks, page 5). This is not

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persuasive because claim 1 does not have a functional limitation and claims 4-7 recite broad functional limitation that comprises various functions.

With regard to the 112, 1st paragraph, enablement rejection, Applicants “asserted that the claims are now commensurate with enablement provided by the disclosure in that the number of protein and DNA species encompassed by the claims are of a number that is reasonable when evaluated under the Wands factors, particularly in view of the predictability in the art, and the abundant guidance in the specification (see page 9, line 21-page 11, line 10, and the examples)” (page 5). This is not persuasive because as discussed in the rejection the art does not allow to predict which modifications will be tolerated without affecting the sucrose binding activity. Further, the specification provides no guidance as to which residues are important for the requisite activity.

The 101 and 112, 2nd paragraph, rejections are withdrawn in view of the amendment.

The 102(b) rejection over Wagener et al. (form PTO-1449 filed January 2, 2002) is withdrawn in view of the amendment. Wagner et al. teach the *scrA* gene (2655 bp) encoding the sucrose-specific enzyme II of the phosphotransferase system from *Staphylococcus xylosus* (480 amino acids) having 36.7% identity with the amino acid sequence of SEQ ID NO:2 of the instant invention. The *scrA* gene will not hybridize to SEQ ID NO:1 under hybridization conditions comprising a wash step in 1.0 x SSC, 0.1% SDS at 60° C as required by claims 4-7.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

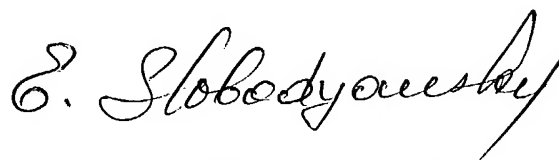
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "E. Slobodyansky". The signature is written in a cursive style with a large, stylized initial "E".

Elizabeth Slobodyansky, PhD

Primary Examiner

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April 28, 2004